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Exhibit D

Elevance Amended Complaint

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ELEVANCE HEALTH, INC., 220 Virginia Avenue Indianapolis, IN 46204, **AMH HEALTH, LLC**, 2 Gannett Drive South Portland, ME 04106, **ANTHEM HEALTHCHOICE HMO, INC.**, Penn 1, 35th Floor New York, NY 10119 **ANTHEM HEALTH PLANS, INC**, 108 Leigus Road Wallingford, CT 06492, **ANTHEM INSURANCE COMPANIES, INC.**, 220 Virginia Avenue, Indianapolis, IN 46204, **BLUE CROSS BLUE SHIELD HEALTHCARE PLAN OF GEORGIA, INC.**, 740 W. Peachtree Street Atlanta, GA 30308, **COMMUNITY CARE HEALTH PLAN OF LOUISIANA, INC.**,	Case No. 1:23-cv-03902-RDM

3850 N. Causeway Boulevard, Suite 1770
Metairie, LA 70002,

FREEDOM HEALTH, INC.

5600 Mariner St. WM11, Suite 227
Tampa, FL 33609

HEALTHKEEPERS, INC.,

2015 Staples Mill Road
Richmond, VA 23230,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, U.S. Department of Health and Human Services

200 Independence Avenue SW
Washington, D.C. 20201,

and

CHIQUITA BROOKS-LASURE, in her official capacity as Administrator, Centers for Medicare and Medicaid Services

7500 Security Boulevard
Baltimore, MD 21244,

Defendants.

AMENDED COMPLAINT

Plaintiffs Elevance Health, Inc. f/k/a Anthem Inc. ("Elevance"), along with its affiliated entities AMH Health, LLC; Anthem Healthchoice HMO, Inc.; Anthem Health Plans, Inc.; Anthem

Insurance Companies, Inc.; Blue Cross Blue Shield Healthcare Plan of Georgia, Inc.; Community Care Health Plan of Louisiana, Inc.; Freedom Health, Inc; Healthkeepers, Inc. (the "Health Plan Plaintiffs," and collectively with Elevance, "Plaintiffs"), by and through their undersigned counsel, hereby submit their Amended Complaint for relief against defendants Xavier Becerra, in his official capacity as Secretary of Health and Human Services ("HHS"), and Chiquita Brooks-LaSure, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services ("CMS"), to challenge unlawful, and arbitrary and capricious final agency action related to the Star Ratings system for Medicare Advantage and Part D health plan contracts, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 551-559 and 701-706.

PRELIMINARY STATEMENT

1. Medicare Advantage Star Ratings are a process implemented by Defendants to rate the overall quality of Medicare Advantage organizations on a scale of 1 to 5 "Stars." CMS calculates Star Ratings by examining data and information relating to individual measures that are intended to assess the overall quality of the plan in several broad categories. A plan's overall Star Rating is a weighted assessment of the individual measures and the Star Rating has significant financial and operational ramifications depending on the score awarded to the plan. For instance, if a Medicare Advantage organization receives a 4-Star rating, it is entitled to Quality Bonus Payments that can amount to millions of dollars or more and which are used to directly benefit Medicare beneficiaries. Plaintiffs bring this action under the Administrative Procedure Act, 5 U.S.C. §§ 702, *et seq.*, to rectify two aspects of Defendants' conduct in issuing 2024 Star Ratings.

2. Defendants calculate "cut points" for certain individual measures to determine whether plan receives a 1, 2, 3, 4, or 5 Star for that specific measure. In calculating the cut points, 42 C.F.R. § 422.166 establishes a "guardrail" such that the cut point from one year to the next

cannot increase or decrease more than 5%. Despite that unambiguous and clear regulatory obligation, CMS set cut points for 2024 Star Ratings that exceed the 5% guardrail—causing a dramatic downward shift in Star Ratings across the industry and with respect to Plaintiffs specifically. Defendants' action is directly contrary to the law and arbitrary and capricious.

3. To calculate cut points, Defendants compare plans to each other. In so doing, Defendants use Tukey statistical methodology, for the stated purpose of introducing stability in the cut points from year to year. The use of Tukey statistical methodology, however, drops mainly low performing plans from the calculations, resulting in skewed cut points, including cut points that are statistically impossible to achieve and introduces instability to the cut points. Moreover, Defendant's application of Tukey to the guardrail methodology is contrary to Defendant's own regulations. Defendant's use of Tukey statistical methodology is directly contrary to law and arbitrary and capricious.

4. Plaintiffs submit this Amended Complaint to withdraw their arguments involving the Star Ratings measure D01, titled "Call Center -- Foreign Language Interpreter and TTY Availability." Plaintiffs have resolved their claim regarding D01 administratively. Based on the evidence presented by Elevance and CMS, the CMS Reconsideration Official found that there was no evidence the call at issue failed due to actions by Elevance and should not have counted against Elevance. The CMS Reconsideration Official concluded that Elevance should have received a 100% success rate for measure D01, meriting a 5-Star rating on that measure. The CMS Reconsideration Official did not review or opine on the issues raised in this Amended Complaint, none of which are subject to administrative exhaustion.[1]

[1] Plans are limited as to what they can challenge in requests for reconsideration and subsequent informal hearings. Specifically, plans can only challenge calculation or data errors that have an effect on a plan's overall Star rating. Plans cannot challenge the methodology for calculating the Star Ratings (including the calculation of the overall Star Ratings), cut points for determining

5. All of the named Plaintiffs, with the exception of Freedom Health, Inc., utilized the same call center and shared the 4-star D01 measure rating that Elevance challenged in its reconsideration request. A change in the 4-star D01 measure rating alone only affected the overall contract Star rating for the 4 enumerated plans involved in the reconsideration request (original Plaintiffs holding contracts H2593, H4036, H5431, and R4487). Nevertheless, a 100% success rate for measure D01, which merits a 5-Star rating on that measure, should be attributed to all of the plans utilizing that call center as required by CMS guidance, which states "all other affected contracts (i.e., contracts of other MA organizations) are recalculated using the corrected data." *See* Centers for Medicare & Medicaid Services, *2021 Quality Bonus Payment Determinations and Administrative Review Process for Quality Bonus Payments and Rebate Retention Allowances*, Nov. 15, 2019 at 7, https://www.hhs.gov/guidance/document/2021-quality-bonus-payment-determinations-and-administrative-review-process-quality-0 (containing identical language to the Centers for Medicare & Medicaid Services, *2025 Quality Bonus Payment Determinations and Administrative Review Process for Quality Bonus Payments and Rebate Retention Allowances,* Nov. 1, 2023 at 7, which is not yet available online). Certain plans that did not have standing to seek reconsideration due to the lack of movement of their overall Star rating may, in fact, change resulting from a combination of measure changes due to Defendants' erroneous actions as set forth herein. With respect to the call the Reconsideration Official determined should not be counted, Defendants' own guidance requires that call to be removed from all Elevance Health contracts that were initially impacted by the call. Based on information and belief, CMS has not updated all

measure thresholds, or the set of measures included in the Star Rating system, among other things. 42 C.F.R. § 422.260(c)(3). Accordingly, CMS does not provide for administrative review of the claims raised in this Amended Complaint and they are reviewable by this Court under 5 U.S.C. § 704.

affected contract' scores for D01 to a 5-Star rating, which is inconsistent with its own guidance and arbitrary and capricious.

JURISDICTION AND VENUE

6. This Court has jurisdiction over this case pursuant to 28 U.S.C. § 1331. This action arises under the Medicare Act, 42 U.S.C. § 1395 *et seq*.; the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 702 and 706; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

7. Venue is proper under 28 U.S.C. § 1391(e).

8. The Complaint was timely filed. *See* 28 U.S.C. § 2401.

9. This Amended Complaint is properly and timely filed under Federal Rule of Civil Procedure § 15(a)(1).

PARTIES

10. Elevance is a healthcare company with its principal place of business in Indianapolis, Indiana. Elevance aims to transform healthcare by becoming a lifetime trusted partner to its members by focusing on whole health, including physical, behavioral, social, and pharmacy, with a goal to improve healthcare affordability, accessibility, quality, and equity.

11. Elevance, through direct and indirect subsidiaries such as the Health Plan Plaintiffs, among other things operates numerous health plans in 22 states and Puerto Rico to provide medical and prescription coverage to approximately 2.9 million Medicare beneficiaries under Medicare Parts C and D. Specifically, the following Health Plan Plaintiffs are direct or indirect subsidiaries of Elevance that enter into contracts with Defendants to provide coverage to Medicare beneficiaries under Medicare Parts C and/or D:

a. AMH Health, LLC has its principal place of business in South Portland, Maine, and has entered into a contract with CMS designated as H9065;

b. Anthem Healthchoice HMO, Inc. has its principal place of business in New York, New York, and has entered into a contract with CMS designated as H8432;

c. Anthem Health Plans, Inc. has its principal place of business in Wallingford, Connecticut, and has entered into contracts with CMS designated as H2836 and H5854;

d. Anthem Insurance Companies, Inc. has its principal place of business in Indianapolis, Indiana, and has entered into contracts with CMS designated as H4909;

e. Blue Cross Blue Shield Healthcare Plan of Georgia, Inc. has its principal place of business in Atlanta, Georgia, and has entered into a contract with CMS designated as H5422;

f. Community Care Health Plan of Louisiana, Inc. has its principal place of business in Metairie, Louisiana, and has entered into a contract with CMS designated as H1947;

g. Freedom Health, Inc. has its principal place of business in Tampa, Florida and has entered into a contract with CMS designated as H5427;

h. Healthkeepers, Inc. has its principal place of business in Richmond, Virginia, and has entered into a contract with CMS designated as H3447;

12. Defendant Xavier Becerra is sued in his official capacity as the Secretary of HHS. This includes overseeing the operations of CMS. Secretary Becerra, in his official capacity, is responsible for implementing and complying with federal law, including the federal laws impacted by this action.

13. Defendant Chiquita Brooks-LaSure is sued in her official capacity as Administrator of CMS, an operating division of HHS. As Administrator, Ms. Brooks-LaSure is responsible for the administration of the Medicare health program, including Medicare Parts C and D. Administrator Brooks-LaSure, in her official capacity, is responsible for implementing and complying with federal law.

FACTUAL ALLEGATIONS

The Medicare Advantage Program

14. The Medicare program, authorized under Title XVIII of the Social Security Act, is a federal health insurance program that generally provides certain healthcare benefits for people age 65 and older and under 65 with certain disabilities or diseases. HHS is the federal agency responsible for administering the Medicare program and does so through CMS.

15. Generally, people who are eligible for Medicare have two options to receive medical benefits. First, under Medicare Parts A and B (often referred to as "original" or "traditional" Medicare), eligible individuals may receive Medicare benefits directly from the federal government. *See* 42 U.S.C. §§ 1395c to 1395i-6 (Part A); 42 U.S.C. §§ 1395j to 1395w-6 (Part B).

16. Alternatively, under Medicare Part C—commonly referred to as the Medicare Advantage program as enacted by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—CMS contracts with private organizations referred to as Medicare Advantage Organizations ("MAOs"). Medicare eligible individuals then may enroll in health plans offered by the MAO and the MAO is responsible for providing Medicare benefits to their enrollees. Congress established the Medicare Advantage program to expand the availability of private health plan options to Medicare beneficiaries, with the goal of controlling spend for the federal

government and generating cost savings for enrollees through market competition and the greater use of managed care. *See* Medicare Program, *Establishment of the Medicare Advantage Program*, 70 Fed. Reg. 4588, 4589 (Jan. 28, 2005) (codified at 42 C.F.R. pts. 417, 422).

17. In addition, under Medicare Part D ("Part D"), Medicare beneficiaries may choose to receive prescription drug benefits under the Medicare Voluntary Prescription Drug Benefit Program. Part D is a voluntary program—meaning that Medicare beneficiaries must choose to enroll in it. Part D is entirely administered by HHS through private organizations called Part D Plans ("PDPs") that can either be stand-alone PDPs or an MAO may offer Part D benefit plans in conjunction with their Part C plans, which are referred to as "MA-PD" plans.

18. MAOs that contract with CMS assume the financial risk of providing healthcare to enrollees that CMS would otherwise bear. MAOs generally receive a per member, per month payment in return for providing coverage to their enrollees for all traditional Medicare services. In addition, MAOs may be eligible to cover additional services beyond those covered by traditional Medicare program if they are eligible to do so through the bid process.

19. In order to enter into contracts with CMS, MAOs must prepare and submit financial bids every year to CMS. In forming their bids, MAOs must analyze their expected revenues and costs related to the services they provide. 42 U.S.C. 1395w–24(a)(6)(A). The bid and its supporting documentation are a complex submission. In addition to the bid amount itself, MAOs must submit a detailed package to CMS stating the specific benefits and cost sharing amounts their plans will cover, for both Medicare Advantage medical coverage and Part D prescription drug coverage. 42 U.S.C. 1395w–24(a)(6)(A).

20. In addition, MAOs must submit a detailed financial breakdown of how the plan arrived at its bid amount, with the actuarial basis and support for those calculations. 42 U.S.C.

1395w–24(a)(6)(A)(ii)-(iii). This must be prepared in accordance with accepted actuarial principles and certified by a qualified actuary. 42 C.F.R. § 422.254(b)(5). Each separate benefit plan offering submitted by a Medicare Advantage plan requires its own bid and supporting documentation. 42 C.F.R. § 422.254(f). The process takes months and bids are due the first Monday of June.

21. If an MAO's bid is below the applicable benchmark—as is often the case—then the plan keeps part of the difference between the bid and benchmark in the form of a rebate that is shared between the federal government and plans. MAOs generally are required to use their portion of the rebate to lower patient cost sharing, lower premiums, provide some coverage for benefits not included in traditional Medicare, or cover certain administrative expenses. Upon acceptance of the MAO's bid and product design, CMS then enters into a contract with the plan for the applicable contract year.

22. The Medicare Advantage program is intended to offer several types of plans to Medicare beneficiaries with expanded benefits beyond those offered by traditional Medicare. To that end, MAOs that submit bids under the federal benchmark and that can provide supplemental benefits beyond those covered by Medicare (such as dental, vision, or medical transportation), as well as reduce member cost-sharing and premiums, are best positioned in the market to attract potential enrollees.

Medicare Advantage Star Ratings

23. In 2008, CMS began publishing annual Star Ratings for MAOs ("Star Ratings"), which are based upon certain data sets to rate each plan on a scale of one to five stars. *See* 42 U.S.C. § 1395w-23(o); *see also* 42 C.F.R. Part 422, Subpart D. The purpose of Star Ratings is to measure the quality of health and drug services received by consumers enrolled in MAOs and

PDPs. According to CMS, "the Star Ratings system helps Medicare consumers compare the quality of Medicare health and drug plans being offered so they are empowered to make the best health care decisions for them . . . [and] to provide Medicare consumers and their caregivers with meaningful information about quality alongside information about benefits and costs to assist them in being informed and active health care consumers." *See 2024 Medicare Advantage and Part D Star Ratings*, CENTERS FOR MEDICARE & MEDICAID SERVICES (October 13, 2023), https://www.cms.gov/newsroom/fact-sheets/2024-medicare-advantage-and-part-d-star-ratings.

24. A plan's annual Star Rating is calculated as the weighted average of its Star Ratings across several individual measures. Specifically, CMS identifies certain measures that it intends to use in any given year for Medicare Advantage, Part D, or MA-PD plans. For instance, for 2024 Star Ratings, MA-PD plans are rated on up to 40 unique quality and performance measures applicable to both Part C and Part D, whereas Medicare Advantage-only contracts are rated on up to 30 Part C measures. Stand-alone PDP contracts are rated on up to 12 Part D measures. *See* CMS Relations, *Fact Sheet - 2024 Medicare Advantage and Part D Star Ratings*, CENTERS FOR MEDICARE & MEDICAID SERVICES (October 13, 2023), https://www.cms.gov/files/document/101323-fact-sheet-2024-medicare-advantage-and-part-d-ratings.pdf (for a full listing of the 40 measures used to determine an MA-PD plan's 2024 Star Rating). Examples of those measures include C01 Breast Cancer Screening (the "percent of female plan members aged 52-74 who had a mammogram during the past 2 years") and C02 Colorectal Cancer Screening ("the "percent of plan members aged 50-75 who had appropriate screening for colon cancer). Each measure is derived from a specified data source identified by CMS in a given year. For example, for 2024 Star Ratings, NCQA HEDIS data for the plan from the year 2022 is used to evaluated measures C01 Breast Cancer Screening and C02 Colorectal Cancer Screening.

25. The individual measures are separated into the following five broad categories: (i) outcomes, which reflect improvements in a beneficiary's health and are central to assessing quality of care; (ii) intermediate outcomes, which reflect actions taken which can assist in improving a beneficiary's health status; (iii) patient experience, which reflect beneficiaries' perspectives of the care they received; (iv) access, which reflect processes and issues that could create barriers to receiving needed care; and (v) process, which capture the health care services provided to beneficiaries which can assist in maintaining, monitoring, or improving their health status.

26. For the 2024 Star Ratings, CMS assigned the highest weight to improvement measures, followed by patient experience/complaints and access measures, then outcome and intermediate outcome measures, and finally process measures. *Medicare 2024 Part C & D Star Ratings Technical Notes*, CENTERS FOR MEDICARE AND MEDICAID SERVICES (Dec. 13, 2023), https://www.cms.gov/files/document/2024technotes20230929.pdf. New measures included in the Star Ratings are given a weight of 1 for their first year of inclusion in the ratings; in subsequent years the weight associated with the measure weighting category is used. In calculating the summary and overall ratings, a measure given a weight of 3 counts three times as much as a measure given a weight of 1. For any given contract, any measure without a rating is not included in the calculation.

27. The Star Rating assigned by CMS to a particular plan is critically important to an MAO. As described more fully below, a plan's Star Rating will have a direct impact upon the amount of payment that CMS makes to an MAO and furthermore directly impacts the premiums and benefits that the plan is able to offer. In addition, the Star Rating is intended to influence beneficiaries' choice to enroll in an MAO's plans.

CMS Uses "Cut Points" When Assigning Stars For Certain Individual Measures

28. To calculate the plans' overall Star Rating, each measure receives a measure-specific Star Rating based upon an analysis of the data identified by CMS for that particular measure. For many measures, CMS calculates "cut points" to determine the Star Rating for the specific measure across all plans. For the majority of Star Ratings measures, CMS determines the measure cut points using the information provided from a hierarchical clustering algorithm which is designed to identify the natural gaps that exist within the distribution of the scores and creates groups (clusters) that are separated into the pre-specified number of categories.

29. For Star Ratings, CMS runs the clustering algorithm with the goal of determining four cut points that are used to create five non-overlapping groups that correspond to each of the Star Ratings. The scores are grouped such that scores within the same Star Ratings category are as similar as possible, and scores in different categories are as different as possible.

30. The groups are then used for the conversion of the measure scores to one of five Star Ratings categories. Star Ratings levels 1 through 5 are assigned with 1 being the worst and 5 being the best. For most measures, a higher score is better, and thus, the group with the highest range of measure scores is converted to a rating of five stars. For some measures a lower score is better, and thus, the group with the lowest range of measure scores is converted to a rating of five stars. Ultimately, the methodology converts measure-specific scores to measure-level Star Ratings so as to categorize the most similar scores within the same measure-level Star Ratings while maximizing the differences across measure-level Star Ratings. If a measure is calculated using cut points, CMS will analyze the data for all applicable MAO contracts to determine the scores needed to achieve a 1, 2, 3, 4, or 5 Star Rating for that particular measure.

CMS Is Required To Apply "Guardrails" That Prohibit It From Changing Any "Cut Point" By More Than 5 Percentage Points From Year To Year

31. In April 2019, CMS adopted the use of "guardrails" to cap the amount of any increases or decreases in measure cut point values from one year to the next.

32. That is, CMS amended 42 C.F.R. § 422.166(a)(2)(i) to require the use of guardrails, or "measure-specific caps in both directions," which ensure that "the measure-threshold-specific cut points do not increase or decrease more than the cap from one year to the next." *See* 84 Fed. Reg. 15680, 15754 (Apr. 16, 2019) (corrections to final rule published in 84 Fed. Reg. 26578 (June 7, 2019)). CMS set a 5-percentage-point absolute cap for measures on a 0 to 100 scale, such that the "measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the [5-percent] cap from one year to the next." 42 C.F.R. § 422.166(a)(2)(i) (2020); *see also* 84 Fed. Reg. at 15830.

33. As CMS explained when it adopted the 5-percentage-point cap, "[g]uardrails at 5 percent provide a balance between providing predictability in cut points while also allowing cut points to keep pace with changes in measure scores in the industry." *Id*. at 15757.

34. In its current form, 42 C.F.R. § 422.166(a)(2)(i) states, in pertinent part:

> Effective for the Star Ratings issued in October 2022 and subsequent years, ***CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap).*** New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

42 C.F.R. § 422.166(a)(2)(i) (2023) (emphasis added).

35. CMS's stated intent in adding guardrails to its Star Rating methodology was to increase the predictability and stability of cut points. *See* 84 Fed. Reg. at 15757 (reflecting CMS's

position in April 2019 that "the guardrails [were] a key component of how [it] intend[ed] the cut point methodology to provide stability and predictability from year to year, in balance with reflecting true performance" and that the guardrails would "lead to increased stability and predictability of cut points"); *see also* 87 Fed. Reg. 79452, 79625 (proposed Dec. 27, 2022) (reflecting CMS's December 2022 acknowledgment that by adding guardrails to its Star Ratings methodology, "[t]he intent of th[e] change in methodology was to increase the predictability and stability of cut points").

CMS's Introduction Of Tukey Statistical Methodology

36. In 2020 rulemaking, CMS introduced the idea that it would add start using the Tukey statistical methodology to identify and then delete outliers during the hierarchical clustering methodology set forth in 42 C.F.R. § 422.166(a)(2), for initial implementation to begin with the 2024 Star Ratings. 85 Fed. Reg. 9002, 9009, 9044 (proposed Feb. 18, 2020); *see also* 85 Fed. Reg. 33796, 33833-36 (June 2020).

37. Generally, an outlier is a data point that differs greatly (much smaller or larger) from other values in a dataset. Using the Tukey statistical methodology, CMS would identify and delete outlier contracts before applying the already-applicable mean resampling and hierarchical clustering processes for all non-CAHPS measures. *Medicare 2024 Part C & D Star Ratings Technical Notes*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 13, 2023), at 18, https://www.cms.gov/files/document/2024technotes20230929.pdf. According to CMS, Tukey outer fence outlier contract scores are those defined as measure-specific scores outside the bounds of 3.0 times the measure-specific interquartile range subtracted from the 1st quartile or added to the 3rd quartile. *Id.*

38. By its design, the Tukey statistical methodology would remove the lower and upper outer fences and would only remove cases that are identified as outliers. 85 Fed. Reg. at 33833. "Values identified as outside the Tukey outer fences would then be removed immediately prior to clustering." *Id.*

39. CMS admitted, however, that based on its own simulations, it found that "there tends [sic] to be more outliers on the lower end of measure scores." *Id*. Removing these outliers effectively removes lower scoring plans from the calculation of cut points. As a result, plans are no longer compared to all competitors and cut points are skewed higher than they would be if all plans were included in the calculation of cut points.[2]

40. The effect of CMS's implementation of Tukey is directly contrary to the stated purpose of the implementation of Tukey, which is to "provide sufficient predictability and stability of cut points from one year to the next." 87 Fed. Reg. 79626, December 27, 2022.

41. Initial implementation of Tukey statistical methodology was to begin with the 2024 Star Ratings. *See* 42 C.F.R. § 422.166(a)(2)(i) ("Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed."). Notably, however, the implementation of Tukey statistical methodology has been fraught with errors and ambiguities during rulemaking. Indeed, despite initially including regulatory text stating that it would implement Tukey statistical methodology beginning in 2024, in subsequent rulemaking CMS actually deleted the applicable language

[2] CMS has other mechanisms for removing true outliers, such as plans serving populations that experienced extreme and uncontrollable circumstances like a natural disaster, from cut point calculations, independent of Tukey Outlier Deletion. In its "Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies," issued on March 31, 2023, CMS explained that "[t]he numeric scores for contracts with 60 percent or more of their enrollees living in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstances are excluded from: (1) the measure-level cut point calculations for non-CAHPS measures…" *See* id at 150.

regarding that methodology from the regulatory text in 42 C.F.R. § 422.166 (effective June 8, 2022). *See* 87 Fed. Reg. 27704, 27895 (May 9, 2022). CMS later added the above language back into the regulatory text in 2023, indicating that the relevant sentence "was inadvertently removed from the codified regulation text." 88 Fed. Reg. 22120, 22295 (Apr. 12, 2023).

Since Adding The Tukey statistical methodology, CMS Considered Whether To Remove The 5-Percent Guardrails But Has Declined To Do So At This Stage

42. In December 2022 proposed rules, CMS proposed to modify the clustering methodology used to set cut points under 42 C.F.R. § 422.166(a)(2)(i) by "eliminating the guardrails that restrict the maximum allowable movement of non-CAHPS measure cut points" beginning with 2026 Star Ratings. 87 Fed. Reg. at 79625-26.

43. In the preamble to the December 2022 proposed rules, CMS expressed its view that implementation of Tukey beginning with the 2024 Star Ratings "minimizes the need for the guardrails to achieve [the predictability and stability of cut points] and weakens the rationale of the guardrails policy at the time the policy was finalized." *Id.* at 79625.

44. Specifically, CMS explained:

> [T]he combination of mean resampling and Tukey outlier deletion, with Tukey outlier deletion being finalized after the bi-directional guardrails policy, ***will provide sufficient predictability and stability of cut points from one year to the next*** when there are not significant changes in overall industry performance, but at the same time allow cut points to adjust when there are significant changes in performance as there was during the COVID–19 pandemic. ***We believe it is important for cut points to be allowed to shift by more than 5 percentage points*** when there are unanticipated, large changes in industry performance in the future.

Id. at 79626 (emphasis added).

45. Accordingly, CMS proposed to amend § 422.166(a)(2)(i) to "modify the language so that guardrails for non-CAHPS measures will only be effective through the 2025 Star Ratings released in October 2024, and not apply for the 2026 Star Ratings or beyond." *Id.* CMS requested feedback on this proposed change. *Id.*

46. Critically, despite soliciting comment on its proposal to remove the 5-percentage point guardrails from the methodology by which it calculates Star Ratings, CMS determined not to amend § 422.166(a)(2)(i) by eliminating the 5-percentage point guardrails, which are still required by law.

47. Rather, CMS stated in the preamble to its April 2023 final rule that various provisions of the proposed rule—including CMS's proposal to "remov[e] guardrails (that is, bi-directional caps that restrict upward and downward movement of a measure's cut points for the current year's measure-level Star Ratings compared to the prior year's measure-threshold specific cut points) when determining measure-specific-thresholds for non-[CAHPS] measures"—are "not being finalized in this [final] rule and instead will be addressed in a later final rule." 88 Fed. Reg. at 22121.

48. As of the date of this filing, CMS has not yet responded to any comments it received in response to its December 2022 proposal to eliminate the 5-percentage point guardrails, much less amended § 422.166(a)(2)(i) to change the rule.

49. Moreover, CMS reaffirmed the importance of the guardrails in its own sub-regulatory guidance published this year for the 2024 Star Ratings, which states:

> ***Guardrails are used to cap the amount of increase or decrease in measure cut point values from one year to the next***. Specifically, each 1 to 5 star level cut point is ***compared to the prior year's value and capped at an increase or decrease of at most 5 percentage points*** for measures having a 0 to 100 scale (absolute percentage cap) or ***at most 5 percent of the prior year's restricted score range*** for measures not having a 0 to 100 scale (restricted range cap). The final capped cut points after comparing each 1 through 5 star level cut point to the ***prior year's values*** are used for assigning measure stars.

Medicare 2024 Part C & D Star Ratings Technical Notes, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 13, 2023), at 19 (emphasis added).

50. Accordingly, CMS was required to apply the 5-percentage point guardrails when it assigned Star Ratings for 2024.

CMS Violated The Guardrail Requirements When Setting 2024 Star Rating Cut Points

51. In October 2023, CMS announced the results of its Star Rating calculations for 2024. In calculating its 2024 Star Ratings, CMS applied the Tukey statistical methodology for the first time. But in determining cut points for the 2024 Star Ratings, CMS violated the guardrail requirement at 42 C.F.R. § 422.166(a)(2)(i), which, notwithstanding the application of the Tukey methodology, still requires CMS to apply a 5-percentage-point guardrail to certain measure cut points so that those cut points "do not increase or decrease more than the value of the cap from 1 year to the next."

52. Specifically, to determine cut points for the 2024 Star Ratings, CMS simulated the 2023 Star Rating cut points assuming it had applied Tukey, and then applied the guardrails to those *simulated* cut points instead of the *actual* 2023 cut points. *See Medicare 2024 Part C & D Star Ratings Technical Notes*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 13, 2023), at 158.

53. Indeed, as set forth in the Technical Notes published by CMS in conjunction with the 2024 Star Ratings, CMS explained:

> For the purposes of calculating the guardrails for the 2024 Star Ratings, the 2023 Star Ratings cut points were rerun including mean resampling, Tukey outlier deletion and no guardrails. These rerun 2023 Star Ratings cut points serve[d] as the basis for applying the guardrails for the 2024 Star Ratings . . . .

Id.

54. By eschewing the *actual* 2023 cut points for *simulated* 2023 cut points—and applying the guardrails to those *simulated* 2023 cut points—the cut points for 2024 Star Ratings increased by "more than the value of the [5-percentage point] cap from 1 year to the next" in direct violation of the plain regulatory language of 42 C.F.R. § 422.166(a)(2)(i).

55. CMS's actions not only violated the express language of the guardrail requirements in 42 C.F.R. § 422.166(a)(2)(i), but also run counter to the very purpose of the guardrails, which was to increase the predictability and stability of cut points from one year to the next. *See* 84 Fed. Reg. at 15757 (reflecting CMS's position in April 2019 that "the guardrails [were] a key component of how [it] intend[ed] the cut point methodology to provide stability and predictability from year to year, in balance with reflecting true performance" and that the guardrails would "lead to increased stability and predictability of cut points"); *see also* 87 Fed. Reg. at 79625 (reflecting CMS's December 2022 acknowledgment that, by adding guardrails to its Star Ratings methodology, "[t]he intent of th[e] change in methodology was to increase the predictability and stability of cut points").

56. Instead of ensuring stability and predictability of cut points from one year to the next, CMS achieved the exact opposite result, causing destabilization of cut points from 2023 to 2024. Indeed, CMS's violation of the guardrails requirement had a significant impact on Star Ratings across the industry by causing overall Star Ratings to drop significantly and making it harder for contracts to improve or even maintain their Star Ratings. For instance, CMS has reported that only 42% of MA-PD contracts that will be offered in 2024 achieved an overall rating of 4 stars or higher, compared with approximately 51% of contracts in 2023. *See 2024 Medicare Advantage and Part D Star Ratings*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Oct. 13, 2023), https://www.cms.gov/newsroom/fact-sheets/2024-medicare-advantage-and-part-d-star-ratings. Weighted by enrollment, the average MA-PD Star Rating fell from 4.14 for 2023 to 4.04 for 2024. Likewise, the number of 5-Star plans fell from 57 in 2023 to 31 in 2024, causing enrollment in 5-Star plans to drop precipitously from 2023 to 2024. *Id.* Moreover, by applying guardrails to the *simulated* 2023 cut points instead of the *actual* 2023 cut points, CMS has artificially inflated the

cut points this year, and those cut points will be utilized for purposes of applying guardrails in future years—thus compounding the problem on a going forward basis.

57. Under the congressionally-mandated "Quality Bonus Payment" program, the Star Ratings that CMS assigns are a key factor in determining CMS's payments to MAOs in two ways and directly impact benefits that MAOs are able to offer to enrollees. *See* 42 U.S.C. § 1395w–23(o). Specifically, if an MAO's contract receives an overall Star Rating of 4 Stars or higher, the federal benchmark is raised 5% resulting in higher payments to the plans. In addition, the rebate amount that plans receive if their bid is below the benchmark is impacted by Star Ratings.

Star Ratings Influence Enrollment In MAOs

58. In addition to their financial impact, Star Ratings also impact enrollment in MAOs. MAOs must recruit and retain enrollees through coordinated outreach and marketing efforts, designed to attract enrollees to pick their plan over competitors' plans. One purpose of Star Ratings is to allow enrollees to identify plans that are purportedly of higher quality relative to other choices. Plans with higher Star Ratings are at a significant advantage in these efforts. Indeed, CMS facilitates the plan selection process by maintaining a website known as the "Medicare Plan Finder," which is an online tool that displays information about available plans, including Star Ratings, to assist beneficiaries in choosing the coverage that is right for them. *See* 42 C.F.R. § 422.166(h). Further, MAOs that receive a 5-Star Rating may be afforded the opportunity to enroll members throughout the year, whereas lower rated plans generally cannot. This offers a significant marketing advantage to 5-Star plans.

59. Moreover, CMS requires that MAOs provide Star Ratings information to beneficiaries through a standardized Star Ratings information document. The wide distribution of Star Ratings information increases the chances that beneficiaries will learn about and rely on Star

Ratings and the low-performing icon, which CMS uses to flag plans it considers low performing, in making plan choices.

Star Ratings Also Influence The Medicare Advantage Bid Process

60. As explained above, each year at the beginning of June, MAOs project their own expected costs for traditional Medicare benefits relative to the benchmark and submit those projections to CMS in the form of "bids" for the payment they require from CMS in the coming year. Since the Star Ratings system influences the revenue a plan expects to receive, knowing the correct Star Rating directly impacts the bid and the services that a plan can ultimately afford to provide.

Elevance's Star Ratings Fell As A Result Of The Introduction of the Tukey Statistical Methodology and the Improper Application Of Guardrails

61. CMS's actions in applying guardrails contrary to the regulatory requirements directly and proximately caused a negative impact on Plaintiffs' Star Ratings. Specifically, had CMS applied the guardrail requirement to the actual 2023 cut points instead of the simulated 2023 cut points, Plaintiffs would have received higher measure-specific Star Ratings for many measures and higher overall Star Ratings for Plaintiffs' contracts listed in Paragraph 10 and due to the impact on Elevance's enterprise weighted average for new contracts.[3]

62. Indeed, while Elevance, through the Health Plan Plaintiffs, holds numerous Medicare contracts that would have received higher Star Ratings had CMS not acted contrary to

[3] CMS does not provide all information necessary to replicate its cut points, as CMS acknowledges in its Medicare 2024 Part C & D Star Ratings Technical Notes. For H8432, upon information and belief, this contact may move from 3.0 to 3.5 Stars; however, due to CMS's failure to provide all necessary information to replicate its cut point calculations, Plaintiffs cannot predict with absolute certainty the contract movement if CMS had not incorrectly calculated cut points. CMS does not provide MAOs with sufficient information to allow full replication and confirmation of CMS's cut point calculations, which necessarily complicates Plaintiffs' ability to successfully appeal its Star ratings and is itself arbitrary and capricious.

law and arbitrary and capriciously as set forth herein. These improperly deflated Star Ratings caused the Health Plan Plaintiffs and Elevance to lose out on hundreds of millions of dollars in Quality Bonus Payments and rebates.

CLAIMS FOR RELIEF

First Claim For Relief

(Violation of Administrative Procedure Act – Agency Action Not In Accordance With Law)

63. Plaintiffs incorporate the Paragraphs 1 through 62 of this Complaint as if set forth fully herein.

64. The APA, 5 U.S.C. §§ 551-559 and 701-706, provides for judicial review to "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action . . . ." 5 U.S.C. § 702. Under 5 U.S.C. § 706(2)(A), an agency action can be held unlawful and set aside if it is "not in accordance with law."

65. CMS is responsible for administering the Medicare program, including the Medicare Star rating system.

66. Under 42 C.F.R. § 422.166(a)(2), CMS is required to apply a 5-percentage-point guardrail to certain measure cut points so that those cut points "do not increase or decrease more than the value of the cap from [one] year to the next."

67. In October 2023 (for 2024 Star Ratings), CMS applied for the first time the Tukey statistical methodology the Star Ratings that it assigned to MAOs. But to determine cut points for 2024 Star ratings, CMS simulated the 2023 Star rating cut points assuming it applied Tukey, and then applied the guardrails to those simulated cut points instead of the actual 2023 cut points.

68. As a result of the simulated cut points and the application of guardrails, the cut points increased by more than 5 percentage points from one year to the next—in violation of the plain regulatory language of 42 C.F.R. § 422.166(a)(2).

69. Plaintiffs were adversely affected as a direct result of CMS's actions, which raise cut points and made it more difficult for Plaintiffs to achieve the prior year's scores despite identical or improved performance. Specifically, due to CMS's improper actions, Plaintiffs have been improperly denied hundreds of millions of dollars in Quality Bonus Payments due to Plaintiffs' contracts and the impact on Elevance's enterprise-weighted average.

70. In addition, CMS failed to calculate cut points for one particular measure, C25, in accordance with the plain language of 42 C.F.R. § 422.162, which requires use of the prior years' data. CMS used the current years' data, which too is contrary to law. This alone negatively impacted Plaintiffs in excess of a hundred million dollars for H5422 due to the impact on this contract and the increase the organization's enterprise weighted average.

71. Accordingly, CMS has acted contrary to law and failed to follow its own rules.

72. Plaintiffs therefore respectfully request the relief as prayed for below.

Second Claim For Relief

(Violation of Administrative Procedure Act – Arbitrary and Capricious Agency Action and Contrary to Law)

73. Plaintiffs incorporate Paragraphs 1 through 62 of this Complaint as if set forth fully herein.

74. Under 5 U.S.C. § 706(2)(A), an agency action can be held unlawful and set aside if it is arbitrary or capricious.

75. CMS's actions as applied to Plaintiffs were arbitrary and capricious, including because they were contrary to law. Moreover, Plaintiffs' cut points are no longer determined by comparison to all their peers, some of which were removed from the cut point calculation simply because they scored lower on relevant Stars measures. This is contrary to one of the main purposes

of the Stars program -- allowing enrollees to identify plans that are purportedly of higher quality relative to other choices.

76. Plaintiffs were adversely affected as a direct result of CMS's actions, which raise cut points and made it more difficult for Plaintiffs to achieve the prior year's scores despite identical or improved performance. Specifically, due to CMS's improper actions, Plaintiffs have been improperly denied hundreds of millions of dollars in Quality Bonus Payments due to Plaintiffs' contracts and the impact on Elevance's enterprise-weighted average.

77. Plaintiffs therefore respectfully request the relief as prayed for below.

Third Claim For Relief

(Declaratory Judgment)

78. Plaintiffs incorporate Paragraphs 1-62 of this Complaint as if set forth fully herein.

79. CMS's calculation of the 2024 Star Ratings is a final agency action made reviewable by 5 U.S.C. § 706(2).

80. Plaintiffs are adversely affected and harmed by the calculation of their Star Ratings.

81. An actual controversy has arisen and exists between the Plaintiffs and Defendants regarding Defendants' calculation of Plaintiffs' 2024 Star Ratings when CMS failed to follow its regulations requiring guardrails be applied to the actual cut points and incorporated Tukey statistical methodology into the calculation of cut points for 2024 Star Ratings.

82. Plaintiffs request a declaration from this Court under 28 U.S.C. § 2201 that Defendants' calculation is arbitrary and capricious.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully ask this Court to:

A. Enter judgment against Defendants and in favor of Plaintiffs for each count alleged in this Complaint;

B. Declare that by calculating Plaintiffs' 2024 Star Ratings that relied upon simulated 2023 cut points using the Tukey statistical methodology and creating cut points that were more than 5 percentage points higher than the actual 2023 cut points, as well as using prior years' data for measure C25, Defendants acted contrary to law and arbitrary and capriciously and order Defendants to recalculate Plaintiffs' Star Ratings without using the Tukey statistical methodology and by using actual 2023 Star Ratings, and including the updated D01 5-Star rating, for all affected plans if necessary.

C. Set aside Defendants' Quality Bonus Payment determination as to Plaintiffs and re-determine Plaintiffs' eligibility for Quality Bonus Payments consistent with the updated Star Ratings after the applicable recalculation.

D. Grant such other and further relief as the Court deemed just and proper.

Dated: March 7, 2023

Respectfully submitted,

ELEVANCE HEALTH, INC. and the HEALTH PLAN PLAINTIFFS

By: *<u>/s/ Lesley C. Reynolds</u>*

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CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of March, 2024, a true and correct copy of this Amended Complaint was filed via the Court's CM/ECF system.

/s/ Lesley C. Reynolds
Lesley C. Reynolds